REMARKS

Claims 1, 4-12, 41-51 and 112 presently appear in this case. No claims have yet been acted upon on the merits. The claims have been subject to a restriction requirement. Reconsideration and withdrawal of the restriction requirement to the extent requested below, and examination and allowance of all of the claims now remaining in the case are hereby respectfully urged.

The examiner considers that the claims are directed to 11 separate inventions:

(i) Group I: Claims 1-12, drawn to a method of inducing or accelerating a healing process of a skin wound comprising insulin administration to the skin wound plus at least one additional agent acting in synergy with said insulin; and claims 85-101, drawn to a method of inducing or accelerating a healing process of a skin wound comprising administering to the skin wound a single dose-unit of insulin;

(ii) Group V: Claims 41-51, drawn to a pharmaceutical composition for inducing or accelerating a healing process of a skin wound comprising insulin and at leas one additional agent acting in synergy with said insulin; and claims 102-111, drawn to a pharmaceutical composition for inducing or accelerating a healing process of a skin wound comprising a single dose-unit of insulin; and

(iii) Groups II-IV and VI-XI: Claims 13-37 and 52-84.

According to the examiner, although the inventions of Groups I and V are related as product and process of use, they are considered distinct since the Group V pharmaceutical composition can be used in the materially different process of insulin therapy for diabetes treatment applied topically. This restriction requirement is respectfully traversed.

In order to be responsive, applicants hereby elect the invention of Group V as defined by the subject matter of claims 41-51. Claims 13-37, 52-84 and 85-111 have now been deleted without prejudice towards the continuation of prosecution thereof in a continuing application. Thus, the only remaining claims are claims 1-12, which the examiner had designated to be in Group I and claims 41-51 which the examiner had designated to be in Group V. The restriction requirement is traversed insofar as claims 1-12 of Group I are concerned.

Group V previously included claims 102-111, which involved a single dose-unit of insulin, and Group I previously included claims 85-101, which included administration of a single dose of insulin. It is believed that it was because of these claims to single dose-units of insulin that the examiner made the comment that the composition of Group V could be used

for the topical treatment of diabetes. In view of the deletion of these claims to single dose-units of insulin, it is believed that there is no other utility for the compositions of Group V than in the method of Group I. The composition requires not only insulin but also at least one additional agent acting in synergy with insulin insofar as inducing or accelerating a healing process of the skin wound is concerned. One of ordinary skill in the art would not consider administering such a composition for the treatment of diabetes. It should be noted that a diabetic ulcer is a symptom of diabetes and not diabetes. It would not be expected that diabetes medicines would be able to topically treat a diabetic ulcer.

Furthermore, to applicants' knowledge there is no known method for treatment of diabetes comprising topical administration of insulin. In order to treat diabetes, insulin has to be injected into the circulation (insulin inhalation as an alternative method is currently under study) and the doses are much higher than the doses used for healing skin wounds. The composition of the present invention is only for topical administration and aimed for treating skin wounds wherein the synergistic effect of insulin and the additional agent used is directed only towards the healing process of the wound. If the examiner desires to retain this restriction

requirement, it is requested that the examiner support the unfounded statement that diabetes can be treated by topical administration of insulin by a citation to literature that would support this contention.

Accordingly, reconsideration and withdrawal of the restriction requirement to the extent requested above is respectfully urged. It is noted, however, that even if the restriction requirement is not withdrawn, the examiner will rejoin claims 1-12 if claims 41-51 are found to be allowable.

It is submitted that all of the claims now present in the case are drawn to a single invention. Prompt consideration on the merits and allowance of all of the claims presently appearing in this case are therefore earnestly solicited.

Respectfully submitted,

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